

WEB Table 1: BBP General Toxicity, Male Rats

Species, Strain, and Source	Experimental Regimen	Animal Number	Dose*	Body Weight	Organ Weight	Histopathology	Hematopoietic System	Chemistry	Other
Fischer 344 Rat Agarwal 1985 (1)	Adult male rats were fed diets with BBP at 0, 0.625, 1.25, 2.5, or 5.0% for 14 days, then were sacrificed and necropsied.	10	0						
		10	447 ^a	NE	↑Li and Ki	NE	NE	↑LH	LOAEL
		10	890 ^a	NE	↑Li and Ki	NE	NE	NE	NE
		10	1,338 ^a	↓	↓Te and SV ↑Li and Ki ↓Th	Dose-related increase in severity of morphological changes in seminal vesicles, testes and prostate.	↓Bone marrow cellularity.	↑FSH ↑LH	↓Food consumption.
		10	1,542 ^b	↓	↓Te, SV, Ep ↑Li, Ki ↓Th	Mild multifocal chronic hepatitis in liver. Cortical lymphocytolysis in thymus (atrophy).	↓Bone marrow cellularity.	↓Test ↑FSH ↑LH	Food consumption.

*Dose in mg/kg bw/day.

^aDoses calculated using pre-treatment body weights (200 g) and average food consumed per group during 14-day study.

^bDose calculated from average body weight during study (since there was a weight loss) and food consumed during the 14-day study.

NE = No Effects

↑ = Statistically Significant Increase

↓ = Statistically Significant Decrease

Li = Liver

Ki = Kidney

Th = Thymus

Te = Testes

Ep = Epididymis

SV = Seminal Vesicle

LH = Luteinizing Hormone

Test = Testosterone

FSH = Follicle Stimulating Hormone

WEB Table 2: BBP General Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Animal Number/ Sex	Dose**	Body Weight	Organ Weight	Histopathology	Hematology	Chemistry	Other
Sprague Dawley Rat	4–6 week-old rats were fed diets with BBP at 2,500–20,000 ppm for 3 months, then were sacrificed and necropsied.	10	0						
		10	188	NE	NE	NE	NE	NA	
		10	375	NE	NE	NE	NE	NA	NOAEL
		10	750	NE	↑Ki(M), Li(F)	NE	NE	NA	LOAEL
		10	1,125	↓(M)*	↑Ki(M), Li	NE	NE	NA	
		10	1,500	↓*	↑Ki(M), Li	NE in liver, testes, or pancreas	NE	NA	
Wistar Rat	4–6 week-old rats were fed diets with BBP at 2,500–12,000 ppm for 3 months and sacrificed and necropsied.	27–45	0						
		27–45	151(M)–171(F)	↓(M)*	↑Li and Ce(F)	NE	NE	NE	LOAEL
		27–45	381(M)–422(F)	↓*	↑Li and Ce(F), Ki	Pancreatic lesions	NE	NE	↓Urinary pH (M)
		27–45	960(M)–1,069(F)	↓*	↑Ce(F), Li, Ki	Hepatic necrosis and pancreatic lesions	Anemia(M)	NE	↓Urinary pH (M)
Sprague-Dawley Rat	6–8 week-old rats inhaled BBP mists at 50, 218, or 789 mg/m ³ for 6 hours/day, 5 days/week for 13 weeks, then were sacrificed and necropsied.	25	0						
		25	9.2(M)/9.8(F)	NE	NE	NE	NE	NE	
Hammond 1987 (2)	5 days/week for 13 weeks, then were sacrificed and necropsied.	25	39.4(M)/42(F)	NE	NE	NE	NE	NE	NOAEL
		25	143(M)/152(F)	NE	↑Li, Ki	NE	NE	↓Serum glucose (M, 13wk)	LOAEL

*Statistical significance is unknown
NE=No Effect
↓=Statistically Significant Decrease

**Dose in mg/kg bw/day
F=Female
Ki=Kidney

^aOrgan to body weight ratio
wk=Week

NA=Not Analyzed
↑= Statistically Significant Increase

M=Male
Li=Liver

Ce=Cecum

WEB Table 3: BBP General Toxicity, Male Rats

Species, Strain, and Source	Experimental Regimen	Animal Number	Dose*	Body Weight	Organ Weight	Histopathology	Epididymal Sperm Count	Hematology	Other	
Fischer 344/N Rat NTP 1997 (3)	Sub-chronic study (26 wk) 6-week-old male rats fed diets with BBP at 0, 300, 900, 2,800, 8,300, and 25,000 ppm. Hematological measurements taken every 30 days. Rats were killed and necropsied at the end of the study, epididymal sperm counts were taken.	13	0							
		14	30	NE	NE	NA	NA	NE		
		14	60	NE	NE	NA	NE	NE		
		14	180	NE	NE	NA	NE	NE	NOAEL	
		15	550	NE	↑Li ^b	NE	NE	NE	↑Hb day 60–180	LOAEL
		11	1,650 ^a	↓	↑Li, Ki ^b ↓Te ^b ↓SV, Ep ^c	Testicular and epididymal degeneration and seminiferous tubule atrophy.	↓ Sperm counts.	↑Macrocytic anemia days 30–180.		

*Dose in mg/kg bw/day.

^aThe dose for the highest exposure level could not be calculated but was estimated from lower doses, assuming equal body weight and food intake.

^bOrgan to body weight ratio.

^cAbsolute organ weight.

NA=Not analyzed

NE=No effects

↑= Statistically significant increase

↓=Statistically significant decrease

M=Male

F=Female

Li=Liver

Ki=Kidney

Te=Testes

Ep=Epididymis

SV=Seminal Vesicle

Hb=Hemoglobin

WEB Table 4: BBP General Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Animal Number	Dose*	Body Weight	Organ Weight	Histopathology	Hematology	Chemistry	Other	
Fischer 344/N Rat NTP 1997 (3)	6-week-old rats were fed diets with BBP at 0, 3,000, 6,000, and 12,000 ppm (M); 0, 6,000, 12,000, and 24,000 ppm (F) for 2 years. Hematological analysis was conducted at 6, 8, and 15 months and hormone levels were measured at 6, 15, and 24 months. Organ weights were measured at 15 months and histopathology was evaluated at 15 and 24 months.		0							
		60	Male: 120	NE	↑Ki	NE	NE	NE		
		60	240	NE	↑Ki ↑Ep	NE	NE	NE	NE	
		60	500	↓	↑Ki, Li ↑Ep	Renal tubule pigmentation (15–24 mo). Hepatic granuloma (24 mo). No testicular effects. Focal pancreatic hyperplasia and <i>some evidence</i> of pancreatic carcinogenicity.	↓RBC (6 mo). ↑Hb (6 mo).	NE	NE	↑Skin lesions.
		60	Female: 300	NE	NE	Nephropathy (24 mo).	NE	NE	NE	
		60	600	NE	NE	Nephropathy (24 mo).	NE	NE	NE	
60	1,200	↓		Renal tubule pigmentation (15–24 mo). Nephropathy (24 mo). <i>Equivocal evidence</i> of pancreatic and urinary bladder carcinogenicity .	↑Microcytic anemia (15 mo).	↓Triiodothyronine (6–15 mo).				

*Dose in mg/kg bw/day.

^aOrgan to body weight ratio.

NA=Not analyzed

↑= Statistically significant increase

NE=No effects

↓=Statistically significant decrease

M=Male

F=Female

Ep=Epididymis

Li=Liver

Ki=Kidney

RBC=Red Blood Cell

mo=Month

Hb=Hemoglobin

WEB Table 5: BBP Developmental Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Numbers ^a	Dose*	Maternal effects	Fetal effects
CD Rat	Prenatal developmental toxicity study. BBP administered in feed on gd 6–15, at 0, 0.5, 1.25, 2.0%. Sacrificed on gd 20. Dams weighed on gd 0, 3, 6, 9, 12, 15, 18, and 20. Maternal liver, kidney, and intact uterus were weighed, corpora lutea were counted and implantation sites examined. All fetuses were weighed and examined for gross external, visceral, and skeletal malformations.	28	0		
Field 1989 (4)		27	420	NOAEL	NOAEL
		30	1,100	↓ Weight gain (37%). ↑ Liver to body weight ratio. ↑ Food and water intake.	Fetuses with variations/litter (41 vs 19%)
		29	1,640	↓ Weight gain (93%). ↓ Corrected weight gain (17%). ↑ Liver to body weight ratio with no pathological effects. ↑ Kidney to body weight ratio. ↑ Food and water intake. Clinical signs of toxicity.	↓ Fetal Weight (20%). ↓ Live fetuses/litter (n=10 vs 15). ↑ Resorptions/litter (40 vs 4%) and litters with resorptions (86 vs 32%). ↑ Fetuses with variations/litter (71 vs 19%). ↑ Fetuses with malformations (53 vs 2%); Litters with malformations (96 vs 25%) (visceral, external, and skeletal, especially of the urinary tract, eyes, and spine).

*Dose in mg/kg bw/day.

^aNumber of dams pregnant at sacrifice.

↑=Statistically Significant Increase

↓=Statistically Significant Decrease

gd=Gestation day

WEB Table 6: BBP Developmental Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Numbers ^a	Dose *	Maternal effects	Fetal effects
Wistar Rats Ema 1990 (5)	Prenatal developmental toxicity study. Rats were fed diets with DBP at 0, 0.25, 0.5, 1.0, 2.0% from gd 0–20. Body weights and food intake were measured daily. Dams were sacrificed on gd 20. Implantation sites were examined. Pups were sexed, weighed, and evaluated for external malformations. Two-thirds of fetuses were examined for skeletal malformations and 1/3 for visceral malformations.	15 (15)	0		
		17 (17)	185	NE	NOAEL
		15 (15)	375	NOAEL	↓Live fetuses/litter (n=11.3 vs 13.9).
		13 (13)	654	↓Weight gain (35%). ↓ Adjusted weight gain (96%). ↓Food Intake.	↓Fetal weight (7%). ↓Live fetuses/litter (n=12.3 vs 13.9). ^c
		13 (0)	974	Weight loss (15 g). Adjusted weight loss (21 g). ^b ↓Food Intake.	Complete postimplantation loss in all litters. Treatment-related increases in malformations, variations, or retardations were not seen at any dose.

*Dose in mg/kg bw/day.

^aNumber of pregnant rats (Number of litters evaluated).

NE=No Effect

n=Number

^bBody weight not including gravid uterus weight.

↓=Statistically Significant Decrease

^cNot statistically significant

↑=Statistically Significant Increase

WEB Table 7: BBP Developmental Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Numbers ^a	Dose *	Maternal effects	Fetal effects
Wistar Rats Ema 1992 (6)	Prenatal developmental toxicity study. Rats were gavaged with BBP on gd 7–15. Body weights and food intake were measured daily. Dams were sacrificed on gd 20. Implantation sites were examined. Pups were sexed, weighed, and evaluated for external malformations. Two-thirds of fetuses were examined for skeletal malformations and 1/3 for visceral malformations.	10 (10)	0		
		10 (10)	500	NOAEL	NOAEL
		10 (7)	750	↓ Body weight gain. ↓ Food intake.	Complete resorption in 3/10 litters. ↑ Fetal death/litter (n=11 vs 1). ↑ Postimplantation loss/litter (82 vs 8%). ↓ Fetal weight (18%). ↑ External (12 fetuses/7 litters vs. 0), skeletal (5 fetuses/4 litters vs. 1), and internal (3 fetuses/3 litters vs. 0) malformations.
		10 (0)	1,000	↑ Death (4 dams). ↓ Corrected body weight gain. ^b ↓ Food intake.	Complete resorption in 6/6 litters.

*Dose in mg/kg bw/day.

^aNumber of pregnant rats (Number of litters evaluated).

n=Number

Gd=gestation day

^bBody weight not including gravid uterus weight.

↓=Statistically Significant Decrease

↑=Statistically Significant Increase

WEB Table 8: BBP Developmental Toxicity, Mice

Species, Strain, and Source	Experimental Regimen	Numbers ^a	Dose*	Maternal effects	Fetal effects
CD-1 Mice Price 1990 (7)	Prenatal developmental toxicity study. BBP administered in feed at 0, 0.1, 0.5, 1.25% on gd 6–15. Sacrificed on gd 17. Dams weighed on gd 0, 3, 6, 9, 12, 15, and 17. Maternal liver, kidney, and intact uterus were weighed, corpora lutea were counted and implantation sites examined. All fetuses were weighed and examined for gross external, visceral, and skeletal malformations.	29			
		28	182	Maternal NOAEL	Developmental NOAEL
		30	910	↓ Weight gain (15%).	↑ Late fetal deaths/litter (2.9 vs 0.7%). ↑ Non-live implants/litter (15 vs 8%) ^b . ↓ Live fetuses/litter (n=12 vs 13). ↑ Fetuses/litter with malformations (14 vs 4%); litters with malformations (60 vs 31%).
		27	2,330	↓ Weight gain (71%). ↓ Corrected weight gain (25%). ↑ Water intake. ↑ Liver and kidney to body weight ratio with no pathological effects.	↑ Resorptions/litter (91 vs 7%); Litters with resorptions (100 vs 55%). ↑ % Non-live implants/litter (93 vs 8%); Litters with non-live implants (100 vs 59%) ^b . ↓ Live fetuses/litter (n=3 vs 13). ↓ Fetal weight (17%). ↑ Fetuses/litter with malformations (89 vs 4%). ↑ Litters with malformations (100 vs 31%), especially external and skeletal defects of the tail, ribs, sternbrae and vertebrae. ↑ Fetuses with variations/litter (98 vs 29%).

*Dose in mg/kg bw/day .

^aNumber of pregnant dams evaluated at sacrifice.

Gd=gestation day

↓=Statistically Significant Decrease

^bNon-live implants include resorptions and late fetal deaths.

↑=Statistically Significant Increase

n=Number

WEB Table 9: BBP Developmental Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Numbers ^a	Dose*	Maternal effects	Fetal effects
Wistar Rat Sharpe 1995 (8)	Pre- and post-natal developmental toxicity study. Female rats were exposed to BBP through drinking water at 0 or 1 mg/L for 2 weeks prior to mating, and during mating, gestation and lactation. Rats were mated to untreated males. Dams were allowed to litter. Litter sizes were evaluated at birth. At 90–95 days of age, male offspring were sacrificed and organ weights were determined.	5	0	NA	↑ Body weight on pnd 22 (11%). ↓ Absolute testes weight (10%) and testes to body weight ratio (8%). - Body weight on pnd 22. - Absolute testes weight and testes to body weight ratio
		5	0.126–0.336		
	After the first litters were weaned, the experiment was repeated in the same dams. Additional parameters monitored included testicular morphology in 2 pups/group and sperm counts in 7–12 pups/group.	6	0.0011 DES ^b	NA	↑ Body weight on pnd 22 (14%). ↓ Absolute testes weight (7%) and testes to body weight ratio (7%). ↓ Daily sperm production (~10–21%). - Body weight on pd 22. - Absolute testes weight and testes to body weight ratio. - Daily sperm production.
		6	0		
		5	0.126–0.336		
	5	0.0011 DES ^b			

*Dose in mg/kg bw/day.

^aTotal litters evaluated. The number of treated dams was not stated.

^bPositive DES control, dose estimated by CERHR.

NA=Not Analyzed

↑=Statistically Significant Increase

↓=Statistically Significant Decrease

WEB Table 11: BBP Developmental Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Numbers ^a	Dose*	Maternal effects	Fetal effects
Wistar Rat TNO 1998 (9)	Pre- and post-natal developmental toxicity study. Female rats were exposed to BBP through drinking water at 0.1, 1, or 3 mg/L for 2 weeks prior to mating, and during mating, gestation and lactation. Rats were mated for 1 week to untreated males, that were only exposed to BBP while breeding. Body weights and food intake were measured weekly and water intake was measured daily. Dams were allowed to litter and following weaning of pups, were killed, necropsied, and implantation sites were examined. Pups were weighed, examined for abnormalities, evaluated for sexual maturation and function, and necropsied at 89–101 days of age.	25	0		
		23	0.012	NE	NE
		22	0.140	NE	↑Pup death on pnd 1–4 (14 vs 0.8%) (Pup death/litter not significant). ↑Large pups (pnd 4).
		24	0.385	NE	↑Pup death on pnd 1–4 (12 vs 0.8%) (Pup death/litter not significant). ↑Cold pups (pnd 1). ↑Large pups (pnd 4). ↑Hair loss.
		21	0.0011-0.0055 DES ^a	~Gestational weight gain. - Duration of pregnancy.	No effects on sperm morphology, number, or motility; estrous cycles; or sexual maturation at any dose level.
	The study was repeated with BBP to verify postnatal pup deaths	26	0		
		22	0.140		↓Pup death on pnd 1–4 (4.6 vs 10%).
	24	0.385		↑Pup death on pnd 1–4 (17 vs 10%). ↑Stillborn pups (n=28 vs 13) (Both effects/litter were insignificant).	

*Dose in mg/kg bw/day.

^aPositive DES control, dose estimated by CERHR.

NE=No Effect n=Number

↑=Statistically Significant Increase ↓=Statistically Significant Decrease

WEB Table 12: BBP Developmental Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Numbers ⁸	Dose**	Maternal effects	Fetal effects
Wistar Rat Bayer 1998 (11)	Pre- and post-natal developmental toxicity study. Female rats were exposed to BBP through drinking water or diet at 0, 1, or 3 ppm for 2 weeks prior to mating, and during mating, gestation and lactation. Rats were mated for up to 3 weeks to untreated males, that were only exposed to BBP while breeding. Body weights and food and water intake were measured every 3–7 days. Dams were allowed to litter and following weaning of pups, were killed, necropsied, and examined for implantation sites. At birth, pups were counted, weighed, and examined for abnormalities. Pups were evaluated for survival and weight gain until pnd 21, when they were sacrificed and necropsied.	21–22 22–25 24	0 0.08–0.09/0.06–0.07/0.11–0.06 ^a 0.10–0.12/0.11–0.11/0.17–0.24 ^b 0.27–0.28/0.19–0.25/0.34–0.49 ^c 0.34–0.35/0.35–0.35/0.54–0.80 ^d	No significant effects on fertility, body weight gain or food and water intake.	Non-significant increase in resorptions in both dose groups. No significant effects on litter size, pup viability from birth to pnd 4, and pup weight.

⁸Number of females that gave birth to a live litter/exposure media.

**Dose in mg/kg bw/day.

^aExposure through 1 ppm diet during prebreed/gestation/lactation.

^bExposure through 1 ppm drinking water during prebreed/gestation/lactation.

^cExposure through 3 ppm diet during prebreed/gestation/lactation.

^dExposure through 3 ppm drinking water during prebreed/gestation/lactation.

pnd=postnatal day

WEB Table 13: BBP Reproductive Toxicity Screening Study, Rats

Species, Strain, and Source	Experimental Regimen	Dose*	Paternal	Effects Maternal	Litters
WU Rat Piersma 1995 (12)	Reproduction screening study. BBP administered by gavage to male and females rats 10–11 weeks old for 2 weeks prior to mating. Males were dosed for a total of 29 days and females were dosed until pnd 6. Rats were housed together 1:1 for a maximum of 2 weeks. Body weight and food intake were measured weekly. Dams delivered and nursed pups. F ₀ were evaluated for fertility and reproductive function, and were killed and necropsied at end of dosing period. Implantation sites were examined and histopathology was conducted. Litters were examined for external malformations, counted, sexed, weighed, and sacrificed and discarded on pnd 6.	0 250 500 1,000	 NE NE ↓Weight gain (21%). ↓ Testis and epididymis weight in F ₀ males (14%). ↑Leydig cell hyperplasia and testicular degeneration.	9/10 females conceived. 8/10 females conceived. 7/10 females conceived. 4/10 females conceived. ↓Gestational weight gain (42%).	 ↓Pup weight on pnd 1(7%). ↓Live pups/litter at birth (n=2 vs 9) and pnd 6 (n=1 vs 9). ↓Pup weight on pnd 1 and 6 (29% and 43%).

*Dose in mg/kg bw/day.

NE=No Effect

pnd=postnatal day

↑=Statistically Significant Increase

↓=Statistically Significant Decrease n=Number

WEB Table 14: BBP Reproductive Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Animal Number	Dose ^b	Effects
Wistar Rat TNO 1993 (13)	One generation reproductive toxicity study. BBP administered in feed at 0, 0.2, 0.4, 0.8% for 10 weeks and 2 weeks before mating in males and females, respectively, and throughout rest of study. Body weight and food intake measured weekly. One male and two females housed together for 3 weeks. Dams nursed pups through pnd 21. Dams were rebred after first litter was weaned. Study was repeated in the same rats. Litters examined counted, sexed, and weighed. After weaning, F ₁ examined for external abnormalities and sacrificed. F ₀ rats were killed and necropsied. Histopathology examined in liver and reproductive tissue of control and high-dose group.	12(M)/ 21–20(F) ^a 12(M)/ 17–22(F) 12(M)/ 20–21(F) 12(M)/ 17–22(F)	0 108/106 116/252 206/217 235/580 418/446 458/1,078	NE NE ↑Liver to body weight ratios in F ₀ females. ↓Weight gain of F ₀ females during gestation and lactation. ↓F _{1b} pup weight on pnd 21 (12%). No effects on implantations, reproductive organ morphology, or fertility, fecundity, and gestation indices.

^aNumber of males and females delivering first and second litter, respectively.

^bDoses (in mg/kg bw/day) for males during premating / females during premating / females during gestation / females during lactation.

NE=No Effect

↑=Statistically Significant Increase

↓=Statistically Significant Decrease

pnd=postnatal day

WEB Table 15: BBP Reproductive Toxicity, Male Rats

Species, Strain, and Source	Experimental Regimen	Animal Number	Dose*	Effects
F344/N Rat NTP 1997 (3)	Sub-chronic reproductive toxicity study (10 wks), in 6-week-old males. BBP was administered in feed at 0, 300, 2,800, and 25,000 ppm for 10 weeks prior to mating. Body weight and food intake were measured weekly. Each male was mated to 2 untreated females for 7 days. Reproductive parameters included fertility and fetal mortality. Males were then killed and examined for hematological, sperm, and histopathological effects. Females were killed and examined for corpora lutea and implantation sites on gd 13 or 13 days after mating.	15	0	
		15	20	NE
		15	200	NOAEL
		15	2,200	↓ Sperm concentration (>99%). Evidence of mating in 10/13 females; no pregnancies. ↓Prostate and testes to body weight ratio. ↓Epididymis and seminal vesicle weight. Testicular and epididymal degeneration. ↓Body weight gain (29%). ↑Liver and thymus to body weight ratio. Mild macrocytic anemia response.

*Dose in mg/kg bw/day

↑=Statistically Significant Increase

↓=Statistically Significant Decrease

Gd=gestation day

WEB Table 16: MBuP Developmental Toxicity, Rats

Species, Strain, and Source	Experimental Regimen	Numbers ^a	Dose*	Maternal effects	Developmental effects
Wistar-King A rats. Imajima et al. (14)	Pre- and post-natal developmental toxicity study with prenatal exposure. Rats were gavaged with 0 or 300 mg/day MBuP in sesame oil from gd 15–18. Testicular descent was evaluated in male offspring on gd 20 or pnd 30–40.	19/15 15/26	0 1,000	Not reported.	Testicular ascent on gd 20. ↑ Cryptorchidism in 22/26 male pups on pnd 30–40 with 87% of the undescended testes in abdominal cavity and 13% in the inguinal ring.

*Dose in mg/kg bw/day.

^aNumber of male fetuses evaluated on gd 20 / pnd 30–40.

Gd=gestation day

↑=Statistically Significant Increase

pnd=postnatal day

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